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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,292	04/10/2001	Alexey Ryazanov	601-1-098CIP	8327

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,292	RYAZANOV, ALEXEY	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/25/2004 has been entered.

Applicants amendment of claims 4 and 16, in the paper of 12/29/2003, is acknowledged and has been entered. Claims 4, 5 and 14-17 are at issue and are present for examination.

Applicants' arguments filed on 12/29/2003, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Revised Manner of Making Amendments

Applicants attention is again directed to the proper method of making amendments to applicants claims. As pointed out to applicants representative in the previous communication from the office, dated 2/11/2004, "Each amendment must include a complete listing of all claims in the application Applicants attention is directed

to 37 CFR 1.121, "Revised Manner of Making Amendments" which is effective July of 2003. See 37 CFR 1.111. With the filing of this request for continued examination, applicants have indicated that they would like the previous amendment to be entered, which it has, however, this amendment was and continues to be in the wrong format as previously indicated to applicants. Applicants are requested for the second time to make all future amendment to the claims are as per **37 CFR 1.121, "Revised Manner of Making Amendments" which is effective July of 2003. See 37 CFR 1.111.**

Priority

The granting of applicants claim of priority for the DNA sequence of SEQ ID NO: 34 to the instant application, filed 4/10/2001, remains proper, as there is no support for this sequence in application Serial No. 09/623,131.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5 and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection was stated in the previous office action as it applied to previous claims 4, 5, and 14-17. In response to this rejection applicants have amended claims 4 and 16 and traverse the rejection as it applies to the newly amended claims.

Applicants amendment and supporting traversal is acknowledged and found somewhat persuasive, however, the rejection of the claims remains, as based on applicants amendment the rejected claims are confusing in that it is unclear it would appear that there are at least two different "mammalian heart alpha kinase" genuses, those that are expressed in the heart and having alpha kinase and those that are not expressed in the heart, presumably expressed in tissues outside or in addition to the heart. Such is supported by applicants specification on page 26 which appears to include additional species then merely those "expressed in the heart". An amendment removing the redundancy of the claim such as "...encoding a mammalian alpha kinase expressed in the heart..." would help applicants overcome the current rejection. It is further noted that applicants current amendment appears to limit the claims to those mammalian alpha kinases that are naturally occurring and expressed in the heart.

Claim 16 is further indefinite in that it is confusing in that it is drawn to a host cell transformed with a recombinant DNA molecule comprising a DNA sequence or degenerate variant thereof, which encodes a heart alpha kinase selected from the group consisting of: a. through d. with c. being DNA sequences that encode an amino acid sequence encoded by any of the foregoing DNA sequences (presumably a. and b.). The claim is confusing in the recitation of "or degenerate variant thereof..." and part c. drawn to DNA sequences that encode an amino acid sequence encoded by any of the foregoing DNA sequences, because it appears that each of these separate recitations

are redundant and thus confusing. Applicants is asked to comment and/or amend the claim such that it is presented in the clearest possible form.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it previously applied to previous claims 16 and 17. In response to this rejection, applicants have amended claim 16 from which claim 17 depends and argue this rejection as it applies to the amended claims. Applicants amendment of claim 16 has been helpful in overcoming the previous grounds of the 112 first paragraph rejection based on a lack of adequate written description rejection based on the "fragment thereof" language. Claims 16 and 17 remain rejected, however, along with claims 4, 14, 15 for the following reasons.

The instant claims are drawn to nucleic acids encoding mammalian heart alpha kinases expressed in the heart and having alpha kinase activity (See above 112 second paragraph rejection) wherein the nucleic acid hybridizes to SEQ ID NO: 34 under

standard hybridization conditions. The claimed genus encompasses naturally occurring allelic variants of nucleic acids that encodes SEQ ID NO: 35.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a single nucleic acid encoding an alpha kinase is fully described in the form of SEQ ID NO:34, wherein the nucleic acid encodes a protein having alpha kinase activity. This description also adequately describes a genus, within the sequence identity (hybridization) limitations of the instant claims, of nucleic acids encoding proteins having this particular function. Those sequences that are "naturally occurring" are a subset of this genus. The specification does not adequately describe this subset according to its structure so that one of skill in the art would be able to

predict naturally occurring sequences, particularly in view of the larger genus that includes both naturally and "manufactured" sequences. Therefore, the instant claims are not adequately described.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 4 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell transformed with a DNA molecule comprising SEQ ID NO: 34, does not reasonably provide enablement for any host cell transformed with any DNA sequences which hybridizes under standard conditions to the DNA sequence of SEQ ID NO: 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it previously applied to previous claims 16 and 17. In response to this rejection, applicants have amended claim 16 from which claim 17 depends and argue this rejection as it applies to the amended claims. Applicants argument has been completely considered. Applicants amendment of claim 16 has been helpful in overcoming the previous grounds of the 112 first paragraph rejection based on a lack of enablement based on the "fragment thereof" language. Claims 16 and 17 remain rejected, however, along with claims 4, 14, 15 for the following reasons.

The instant specification teaches SEQ ID NO:35, an alpha kinase expressed in the mammalian heart, and SEQ ID NO:34 encoding SEQ ID NO:35. The art includes few examples of mammalian alpha kinases expressed in the heart. The art fully enables any DNA encoding SEQ ID NO:35, based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other nucleic acids encoding mammalian alpha kinases expressed in the heart using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the nucleic acids within the scope of the claims because the ability to find a nucleic acid which encodes a mammalian alpha kinase which is expressed in the heart, which is structurally related to SEQ ID NO:34, is not equivalent to the ability to make the claimed genus of nucleic acids as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its alpha kinase and heart expression is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those nucleic acid molecules having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
9/17/2003